

## UNITED STATE DEPARTMENT OF COMMERCE **Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.
09/300,173	04/27/99	BYUN		Υ .	T <del>9</del> 005
- 020450 ALAN J HOWARTH PO BOX 1909		HM22/0804		EXAMINER	
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SANDY UT 84091				ART UNIT	PAPER NUMBER
				1623	3
				DATE MAILED:	08/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

## Office Action Summary

Application No. 09/300,173

Applica. .s)

Byun et al.

mmary Examiner

Kathleen Kahler Fonda

Group Art Unit 1623



X Responsive to communication(s) filed on 7-9-99			
This action is FINAL.			
Since this application is in condition for allowance except for for in accordance with the practice under Ex parte Quayle, 1935 C.	.D. 11; 453 O.G. 213.		
A shortened statutory period for response to this action is set to exist longer, from the mailing date of this communication. Failure to rapplication to become abandoned. (35 U.S.C. § 133). Extensions 37 CFR 1.136(a).	espond within the period for response will cause the		
Disposition of Claims			
	is/are pending in the application.		
Of the above, claim(s)	is/are withdrawn from consideration.		
Claim(s)			
¹⊠ Claim(s) 1-5 and 7-20			
X Claim(s) 6			
☐ Claims	are subject to restriction or election requirement.		
Application Papers  X See the attached Notice of Draftsperson's Patent Drawing R  The drawing(s) filed on is/are objected			
<ul> <li>☐ The proposed drawing correction, filed on</li> <li>☐ The specification is objected to by the Examiner.</li> <li>☐ The oath or declaration is objected to by the Examiner.</li> </ul>			
Priority under 35 U.S.C. § 119  Acknowledgement is made of a claim for foreign priority und All Some* None of the CERTIFIED copies of the received.  received in Application No. (Series Code/Serial Number received in this national stage application from the Interest *Certified copies not received:  Acknowledgement is made of a claim for domestic priority to	er) ternational Bureau (PCT Rule 17.2(a)).		
Attachment(s)  Notice of References Cited, PTO-892  Information Disclosure Statement(s), PTO-1449, Paper No(s  Interview Summary, PTO-413  Notice of Draftsperson's Patent Drawing Review, PTO-948  Notice of Informal Patent Application, PTO-152			
SEE OFFICE ACTION ON THE	E FOLLOWING PAGES		

Art Unit: 1623

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-11, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by DIANCOURT et al. (K). DIANCOURT teaches compounds referred to therein as CHOHEP and STEHEP, which are cholic acid and stearic acid covalently bound to heparin, respectively; see Scheme 2 and the first full paragraph on page 209. A molecular weight within the broad range of claim 4 is an inherent property of the heparin employed by DIANCOURT. With regard to claim 9, although the mole ratio of the reference cannot be calculated precisely based on the information provided, it flows inherently from the inherent molecular weight. As for claims 10, 11, and 16, DIANCOURT teaches an aqueous solution of CHOHEP in the fourth paragraph on page 216. The claims are therefore anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1623

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DIANCOURT et al. (K) in view of CASEY et al. (B).

Applicant claims a pharmaceutical composition comprising a hydrophobic agent selected from the group consisting of bile acids, sterols, and alkanoic acids covalently bound to a polysaccharide, and a carrier. Claim 13 requires that the

Art Unit: 1623

carrier be a sustained release polymeric matrix, and claim 15 requires that the polymeric matrix be a poly((ethylene oxide) - poly(e-caprolactone)) copolymer. In claim 16, the polysaccharide is required to be heparin. Applicant also claims a method of inhibiting blood coagulation on a medical device by coating the device with such a pharmaceutical composition.

DIANCOURT teaches as set forth above. DIANCOURT does not teach a sustained release polymeric matrix as a carrier, or a coating for a medical device.

At column 1, lines 9-25, CASEY suggests the use of a poly((ethylene oxide)-poly(e-caprolactone)) copolymer as a biodegradable hydrogel material for sutures or suture coatings.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to substitute a hydrogel such as a poly((ethylene oxide)-poly( $\varepsilon$ -caprolactone)) copolymer as taught by CASEY for the carrier of DIANCOURT. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because CASEY had suggested the utility of such carriers as biodegradable hydrogel materials, and that the could be used as coatings for sutures.

Claims 10-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DIANCOURT et al. (K) in view of PATNAIK et al. (A).

Art Unit: 1623

Applicant claims as set forth above.

DIANCOURT teaches as set forth above. DIANCOURT does not teach a sustained release polymeric matrix as a carrier, or a coating for a medical device.

At column 9, lines 31-37, PATNAIK teaches a pharmaceutical composition comprising heparin covalently via an amide linkage to a polyurethane polymer (polyesterurethane). PATNAIK further teaches coating the composition onto a medical article at column 12, lines 22-34.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to substitute a polyurethane polymer as taught by PATNAIK, or other art-recognized biocompatible polymer, for the carrier of DIANCOURT. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because PATNAIK had suggested the pharmaceutical utility of such carriers, and that they could be used as antithrombotic coatings for medical articles.

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No prior art of record teaches or suggests heparin covalently bound to a sterol as in claim 6.

Art Unit: 1623

Berlowitz-Tarrant et al. (C) is cited to indicate the state of the art at the time of the invention more completely. The reference teaches a variety of polymers which may be used for preparation of non-thrombogenic biomedical articles.

To summarize, claim 6 is objected to, but recites allowable subject matter. Claims 1-5 and 7-20 are rejected.

Papers relating to this application may be submitted to

Technology Center 1600 by facsimile transmission. The number of
the fax machine for official papers in Technology Center 1600 is

(703) 308-4556. Any document submitted by facsimile transmission
will be considered an official communication unless the cover
sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Tuesday through Friday, and on

Application/Control Number: 09/300,173 Page 7

Art Unit: 1623

alternating Mondays, from 7:30 a.m. until 5:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Gary Geist at (703) 308-1701. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D.

Primary Examiner Art Unit 1623